

**REMARKS**

Reconsideration and withdrawal of the rejections set forth in the Office action dated February 8, 2005 are respectfully requested. Applicants petition the Commissioner for a 2-month extension of time. A separate petition accompanies this amendment.

**I. Amendments**

Claims 26, 34, 38, and 42 are amended for clarity and to recite the composition/oil composition/dietary supplement/food composition, is provided in a daily dose of 0.15 to 0.3 g/kg. Support for this amendment can be found on page 4, line 32 through page 5, line 3.

Claims 28, 29, 32, 33, 36, 37, 40, 41, 44, and 45 are amended to recite a weight ratio of linoleic fatty acid to  $\alpha$ -linolenic fatty acid of 0.5-2.0. Basis for this amendment can be found on page 3, line 29 through page 4, line 1 and Figures 1-4.

Claims 35-37 are amended for consistent terminology.

No new subject matter has been added by way of these amendments.

**II. Rejections under 35 U.S.C. §102**

Claims 26, 28-29, 34, 36-38, 40-42, and 44-45 were rejected under 35 U.S.C. §102(b) as allegedly anticipated by Martin (U.S. Patent No. 4,061,738) as evidenced by Bhatti et al. (JAOCS, 67(6):364-367, 1990) and Carughi et al. (GB Patent No. 2274235).

**A. The Present Claims**

The present invention, as embodied in claims 26, 34, 38, and 42, relates to a composition (claim 26), an edible oil composition (claim 34), a dietary supplement (claim 38), and a food composition (claim 42) comprising flaxseed oil, wherein the composition/supplement has a total weight ratio of linoleic fatty acid (n-6, 18:2) to  $\alpha$ -linolenic fatty acid of 0.05-7.5, and wherein the composition/supplement is provided

in a daily dose of 0.15 to 0.3 g/kg. Thus, the present claims require the following elements:

1. flaxseed oil
2. a linoleic/linolenic fatty acid weight ratio of 0.05-7.5; and
3. wherein the composition/supplement is provided in a daily dose of 0.15 to 0.3 g/kg.

#### B. The Prior Art

Martin describe a process for reducing platelet adhesiveness by orally administering an effective amount of an enriched, edible flaxseed oil.

#### C. Analysis

According to the M.P.E.P. § 2131, "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference".

Martin fail to teach a composition/supplement as presently claimed wherein the composition/supplement is provided in a daily dose of 0.15 to 0.3 g/kg. The only mention of dose by Martin is 15 ml/day or at least 70% of the 15 ml/day.

Accordingly, Applicants submit that standard of strict identity to maintain a rejection under 35 U.S.C. §102 has not been met. Withdrawal of the rejection under 35 U.S.C. §102(b) is respectfully requested.

#### III. Rejections under 35 U.S.C. §103

Claims 26, 34, 38, and 42 were rejected under 35 U.S.C. §103 as allegedly obvious over Leach (U.S. Patent No. 5,612,074).

Claims 27, 31, 35, 39, and 43 were rejected under 35 U.S.C. §103 as allegedly obvious over Leach in view of Erasmus *et al.* (U.S. Patent No. 5,656,312) and Hunter *et al.* (U.S. Patent No. 4,863,753).

Claims 28, 30, 32, 36, 40, and 44 were rejected under 35 U.S.C. §103 as allegedly obvious over Leach and further view of Igarashi (U.S. Patent No. 6,159,507).

Claims 29, 33, 37, 41, and 45 were rejected under 35 U.S.C. §103 as allegedly obvious over Leach, Erasmus et al. and Hunter et al., and further view of Igarashi.

A. The Present Claims

The present claims are summarized above.

B. The Cited Art

LEACH A detailed summary of the Leach reference was provided in the amendment submitted February 18, 2003. A brief summary is provided here for convenience.

Leach describes a food bar having a ratio of dry ingredients to liquid ingredients of 3:1 (Col. 2, lines 65-67). Leach further teaches that considering both the oil seeds of the mixture of dry ingredients and the vegetable oil of the mixture of liquid ingredients, polyunsaturated linoleic acid is present in the food bar in a ratio of about 3:1 by weight to super-unsaturated alpha-linolenic acid (Col. 5, lines 12-16).

ERASMUS ET AL. describe a composition and method for preparing a food supplement. The supplement includes at least 70% by weight of an oil seed constituent which may be flax seed or perilla seed.

HUNTER ET AL. disclose a peanut butter with reduced calories through reduction of the amount of peanut oil and total oil. This is achieved by replacement of at least a portion of the peanut oil with triglycerides containing medium chain fatty acids. The remaining fatty acids may be long chain fatty acids such as linoleic and linolenic acid. It is preferred that peanut butter contain from about 5% to about 25%

linoleic acid and up to about 15% linolenic acid. The peanut butter further generally contains up to about 5% of a stabilizer consisting of an oil such as rapeseed oil. It is disclosed that linolenic oil is found in linseed oil and perilla oil.

IGARASHI describes a "balance modifier" that can be added to food in order to adjust the *in vivo* ratio of omega-6 unsaturated fatty acids to omega-3 unsaturated fatty acids.

### C. Analysis

As stated in M.P.E.P. § 2143, "to establish a prima facie case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Third, the prior art references (or references when combined) must teach or suggest all the claim limitations."

#### 1. Rejection over Leach

As discussed above, the claimed invention includes a composition, edible oil, dietary supplement, or food composition comprising:

1. flaxseed oil
2. a linoleic/linolenic fatty acid weight ratio of 0.05-7.5; and
3. wherein the composition/supplement is provided in a daily dose of 0.15 to 0.3 g/kg. As described on page 5, lines 7-13, Applicants have found that this dosage optimizes the significant effects of the present composition/supplement in enhancing cognitive, learning and memory function in adults. As described on page 7, line 11 through page 10, line 8, compounds as described above were administered to pregnant and newborn rats at 0.15 g/kg of body weight. The percentage of DHA concentration in the brain increased from the starting concentration at each of the linoleic:α-linolenic weight ratios as shown in Figs. 1 and

2. Further, the cognitive ability of the rats increased as measured by a decrease in reaction time evaluated with the Morris maze test. As shown in Figs. 3A-3B, the reaction time decreased significantly at the doses used, especially for the 2.0 and 7.5 linoleic:α-linolenic weight ratios.

Applicants first maintain that Leach fails to teach the claimed linoleic:α-linolenic weight ratio for reasons of record. Briefly, the food bar taught by Leach contains numerous ingredients that would affect the ratio of linoleic/linolenic fatty acid. Nowhere does Leach teach that the final food bar composition must contain a final linolenic and/or linolenic acid weight ratio of between 0.05-7.5. The teaching in Leach with respect to linoleic and/or linolenic acid ratio is limited to a teaching of a 3:1 ratio for the oil seeds of the dry ingredients and the vegetable oil of the liquid ingredients (see Col. 3, lines 41-47 and Col. 5, lines 12-16). Leach fails to consider the effect of lecithin or any of the other linoleic and/or linolenic acid-contributing ingredients on the final linoleic and/or linolenic acid ratio in the food bar. Based on calculations of the linoleic:linoleic percentages of all the ingredients listed in the first exemplary food bar (see Col. 5, line 23 et seq) has a linoleic fatty acid to α-linolenic fatty acid weight ratio of at least 8.6.

Further, Leach fails to teach any of a composition, edible oil composition, dietary supplement, or food composition provided in a daily dose of 0.15 to 0.3 g/kg. Instead, Leach teaches a food bar of about 62 grams.

As Leach does not recognize the increased cognitive abilities obtained by the compositions/supplements of the present claims, it cannot be obvious to modify Leach along the lines of the present claims.

## 2. Rejection over Leach in view of Erasmus et al. and Hunter et al.

As noted above, Leach fails to teach a composition, edible oil, dietary supplement, or food composition with the claimed linoleic fatty acid to α-linolenic fatty acid weight ratio provided in a daily dose of 0.15 to 0.3 g/kg.

The combined and/or separate teachings of Erasmus *et al.* and Hunter *et al.* do not make up for this deficiency as neither reference teach a composition/supplement provided at the claimed daily dose or the claimed ratio.

3. Rejection over Leach in view of Igarashi

As noted above, Leach fails to teach a composition, edible oil, dietary supplement, or food composition provided in a daily dose of 0.15 to 0.3 g/kg.

The combined and/or separate teaching of Igarashi *et al.* does not make up for this deficiency. The composition of Igarashi comprises an active ingredient of a dioxabicyclo(3,3,0)octane derivative as a "balance modifier" and not a composition or supplement having a linoleic fatty acid to  $\alpha$ -linolenic fatty acid weight ratio as presently claimed. Igarashi *et al.* teach the balance modifier is administered in a total amount of 1 mg to 10 g/day.

4. Rejection over Leach and Erasmus *et al.* and Hunter *et al.* in view of Igarashi

As noted above, the combined teaching of Leach, Erasmus *et al.*, and Hunter *et al.* fails to teach a composition, edible oil, dietary supplement, or food composition provided in a daily dose of 0.15 to 0.3 g/kg.

The combined and/or separate teaching of Igarashi *et al.* does not make up for this deficiency as described above.

Since the combined and/or separate teachings of the cited references fail to teach all of the claimed elements, the standard for obviousness has not been satisfied and withdrawal of the rejection under 35 U.S.C. §103 is respectfully requested.

IV. Conclusion

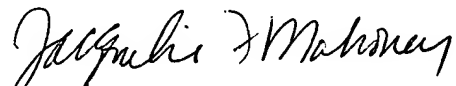
In view of the foregoing, Applicants submit that the claims pending in the application are in condition for allowance. A Notice of Allowance is therefore respectfully requested.

If in the opinion of the Examiner, a telephone conference would expedite the prosecution of the subject application, the Examiner is encouraged to call the undersigned at (650) 838-4410.

Respectfully submitted,

Date: \_\_\_\_\_

July 7, 2005

  
Jacqueline F. Mahoney  
Registration No. 48,390

**Correspondence Address:**

Customer No. 22918

Phone: (650) 838-4300